

Appl. No. 10/710,778  
Amdt. dated September 10, 2006  
Reply to Office action of June 12, 2006

**Amendments to the Specification:**

A copy of the original specification with pages numbered is submitted herewith.

Please replace paragraph [0004] with the following amended paragraph:

[0004] Psoriasis is clinically addressed with topical medications, phototherapy, systemic medications. Agents such as steroidal drugs, cyclosporine, ~~Methothrexate~~ methotrexate, oral and topical retinoids, selenium sulfide used in pharmaceutical preparations for this purpose have various side effects. There is no known cure for psoriasis.

Please replace paragraphs 15, 18, 20, 24, 35, 36, 37, 39-42, 44, 48, 54 with the respective amended paragraphs as follows:

[0015] WO 00/57893 describes compositions containing Boswellia serrata extract wherein Boswellia serrata extract, boswellic acid or a derivative thereof is useful in preparing skin care or hair care compositions with the ability to provide a soothing effect to irritated skin.

[0018] Recent studies suggest that that psoriasis is not primarily a skin disorder but an immunological disturbance under the skin. The skin manifestations are a result of overstimulation of superficial skin cells (Langerhans cells) due to increased production of interleukin 2, 6 and 8 as well the diminished production of transforming growth-factor-alpha Interleukin-10 (Christ, 1999).

[0020] Tumor necrosis factor-alpha (TNF-alpha) and its receptors play important roles in the induction and maintenance of psoriatic lesions. A recent study reports that oral supplementation with selenomethionine was ineffective as adjuvant treatment in plaque psoriasis and may contribute to the maintenance of elevated TNF-R1 (soluble TNF-alpha receptor type 1) concentration in psoriasis patients despite the remission of skin lesions. (Serwin et al., 2003).

[0024] United States Patent: 6,630,442 describes a composition of glutathione and selenium, as a selenoamino acid or selenium yeast extract and an epidermal growth factor

in a topical carrier and method of using the composition to reduce and repair skin damage, resulting from aesthetic (exfoliation and chemical peels) and surgical (laser and other therapies) procedures and other chemical and thermal burns to the cutaneous tissues.

[0035] Reilly DM. et al. (2000) Inflammatory mediators in normal, sensitive and diseased skin types. *Acta Derm Venereol* 80(3):171-4.

[0036] Iversen L, et al. (1997) Significance of leukotriene-A4 hydrolase in the pathogenesis of psoriasis. *Skin Pharmacol.* 10(4):169-77.

[0037] Wiedow O, et al. (1992) Lesional elastase activity in psoriasis, contact dermatitis, and atopic dermatitis. *Invest Dermatol.* 99(3):306-9.

[0039] Safayhi, H. et al. (1997) Inhibition by boswellic acids of human leukocyte elastase. *J. Pharmacol. Exp. Ther.* 281:460-463.

[0040] Corrocher, R. et al. (1989) Effect of fish oil supplementation on erythrocyte lipid pattern, malondialdehyde production and glutathione-peroxidase activity in psoriasis. *Clin Chim Acta* 179(2):121-31.

[0041] Serwin AB, et al. (1999) Selenium nutritional status and the course of psoriasis. *Pol Merkuriusz Lek.* 6(35):263-5.

[0042] Burke, K.E. et al. (1992) The effect of topical L-selenomethionine on minimal erythema dose of ultraviolet irradiation in humans. *Photodermatol Photoimmunol Photomed.* 9(2):52-7.

[0044] Christ HW. (1999) Immunomodulating therapy of psoriasis vulgaris. *Med Klin* 94 Suppl 3:90-2.

[0048] The invention describes compositions and methods for the management of hyperproliferative skin conditions such as psoriasis, and their associated symptoms. The compositions described herein contain a natural leukotriene inhibitor selected from *Boswellia serrata* gum resin, its extractives, isolates or derivatives in combination with a bioavailable organic selenium nutritional supplement. These compositions are administered orally and topically to the individual human or animal in need of treatment at optimal levels to manifest the desired benefits, with no untoward side effects.

[0054] The current invention addresses hyperproliferative skin conditions with a novel treatment regimen in which a natural dual acting inhibitor of 5-lipoxygenase and human leukocyte elastase is ingested orally, as well as applied topically, in combination with a bioavailable organic selenium supplement which is ingested orally.

Please replace paragraph [0060] with the following amended paragraph:

[0060] An exemplary embodiment of the formulation for topical application is presented in Table 2.

**Table 2: Composition of the topical cream**

<b>Ingredient</b>	<b>% (w/w)</b>
Purified water	60.000
Carbomer 940	0.250
Glycerin	4.000
Methylparaben	0.200
Edetate sodium	0.010
Cetyl alcohol	3.500
Stearyl alcohol	3.500
Stearic acid	6.500
Glyceryl stearate	2.500
PEG-100 stearate	2.500
Isopropyl palmitate	6.000
Vitamin E acetate	1.000
Dimethicone	0.100
Propylparaben	0.100
Vitamin A Palmitate	0.100
Ascorbyl palmitate	0.200
<del>Boswellin</del> <b>BOSWELLIN</b>	5.000
Purified water	2.000
Triethanolamine	0.400
Imiduria	0.300

~~Boswellin~~ **BOSWELLIN** (a trademark of Sabinsa Corporation, NJ, USA) is a standardized Boswellia serrata gum resin extract containing beta-boswellic acid, acetyl-beta-boswellic acid, 11-keto-beta-boswellic acid and Acetyl-11-keto-beta-boswellic acid.